

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Master Dkt. 1:13-md-02419-RWZ

THIS DOCUMENT RELATES TO:

All actions naming Saint Thomas Outpatient
Neurosurgical Center

**PLAINTIFFS' STEERING COMMITTEE'S
RESPONSE TO SAINT THOMAS OUTPATIENT NEUROSURGICAL DEFENDANTS'
STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF THEIR
CROSS MOTION FOR SUMMARY JUDGMENT**

The Plaintiffs' Steering Committee (the "PSC") respectfully submits this Local Rule 56.1 response to the Saint Thomas Outpatient Neurosurgical Defendants' Statement of Undisputed Facts in Support of Their Cross Motion for Summary Judgment [Dkt. No. 2467].⁷ The PSC responds as follows to each of the statements:

1. STOPNC is an ambulatory surgery center licensed under Tennessee Code Title 68, Chapter 11 and accredited by the Joint Commission.⁸

RESPONSE: Admitted for purposes of Summary Judgment.

2. John W. Culclasure, MD is an anesthesiologist licensed pursuant to Tennessee Code Title 63.⁹

RESPONSE: Admitted for purposes of Summary Judgment.

⁷ Throughout their Statement of Undisputed Facts the Saint Thomas Outpatient Neurosurgical Defendants refer to Saint Thomas Outpatient Neurosurgical Center as "STOPNC," the PSC will refer to this center as "Saint Thomas Neurosurgical."

⁸ Culclasure Aff. ¶ 4.

⁹ Culclasure Aff. ¶ 2.

3. The Plaintiffs underwent steroid injection procedures at STOPNC for treatment of back or neck pain.¹⁰

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion. The PSC admits for purposes of summary judgment that certain individuals received steroid injections at Saint Thomas Neurosurgical for purposes of treating back or neck pain, but not all Plaintiffs received steroid injections for these ailments, as others received periphery joint injections or sought treatment for other pain issues.¹¹

4. For example, Plaintiff Mae Parman was referred to STOPNC for epidural steroid injections to treat back, hip, and leg pain, believed to have been caused by lumbar stenosis.¹²

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion and involves a specific Plaintiff and therefore not appropriate for common motion for summary judgment. Regardless, the PSC will admit the substance of this statement for the sole purpose of summary judgment.

5. Prior to undergoing epidural steroid injection procedures at STOPNC, the Plaintiffs signed a consent form.¹³

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion and involves allegations related to individual Plaintiffs. The PSC does not have access to all relevant medical records to determine whether every Plaintiff involved in this litigation executed a consent form. Regardless, the PSC will admit that some plaintiffs signed consent forms that did not inform patients that they would receive epidural steroids manufactured by a compounding pharmacy, rather than FDA approved products made by licensed pharmaceutical companies such as Pfizer.¹⁴

6. During the Plaintiffs' procedures, an anesthesiologist administered methylprednisolone acetate ("MPA") procured by STOPNC from the New England

¹⁰ 2nd Am. Master Complaint ¶¶ 151-154; Culclasure Aff. ¶¶ 7-8.

¹¹ See e.g., *Ziegler v. Ameridose*, Case No. 1:13-cv-12588, Dkt. No. 1, ¶¶ 157 and 161.

¹² Culclasure Aff. ¶ 8.

¹³ Culclasure Aff. ¶ 9.

¹⁴ Dkt. No. 2464-1 at PageID 18.

Compounding Center (“NECC”).¹⁵

RESPONSE: Admitted that Plaintiffs received injections from an anesthesiologist and that the injection was MPA that Saint Thomas Neurosurgical purchased from NECC.

7. Dr. Culclasure performed many of those procedures.¹⁶

RESPONSE: Admitted for purposes of Summary Judgment.

8. STOPNC paid \$6.50 per one mL vial of MPA from NECC.¹⁷

RESPONSE: Admitted for purposes of Summary Judgment.

9. Each vial contained 80 mg of MPA.¹⁸

RESPONSE: Admitted for purposes of Summary Judgment.

10. Two fees were charged for the epidural steroid injections: a physician fee by Dr. Culclasure, and a facility fee by STOPNC.¹⁹

RESPONSE: Denied. The PSC admits that Dr. Culclasure billed separately for the medical services associated with administering the injections. In addition, billing statements for plaintiffs such as Mae Parman indicate a charge for “INJECTION, SINGLE” or “INJECTION SINGLE DIAGNOSTIC OR”²⁰ Those billing statements say nothing about a “facility fee.”²¹ According to contracts between Saint Thomas Neurosurgical and payors such as Blue Cross Blue Shield of Tennessee, the injection charges specifically include reimbursement for drugs provided to patients.²²

11. Dr. Culclasure charged the Plaintiffs and/or their insurers the physician fee for his

¹⁵ 2nd Am. Master Compl. ¶¶ 153, 174; Culclasure Aff. ¶¶ 6,7.

¹⁶ Culclasure Aff. ¶ 7.

¹⁷ Culclasure Aff. ¶ 6.

¹⁸ Culclasure Aff. ¶ 6.

¹⁹ Culclasure Aff. ¶¶ 10, 11.

²⁰ Dkt. No. 2464-1 at PageID 21 and 23.

²¹ *Id.*

²² Williams Tr., Ex. 517. The PSC previously filed this document under seal with the Court at Dkt. No. 2261-7.

professional services during the epidural steroid injection procedures.²³

RESPONSE: Admitted for purposes of Summary Judgment.

12. STOPNC charged the Plaintiffs and/or their insurers a facility fee of approximately \$1,034,²⁴ which was a single, global fee for the epidural steroid injections that covered all aspects of the procedure furnished by STOPNC, including:

- a. A licensed registered nurse to assess the patient's condition prior to the procedure and after the procedure, and to discharge the patient
- b. A certified medical assistant, licensed practical nurse, or a certified radiology technician to assist the physician in performing the procedure
- c. Use of STOPNC's facility, including patient rooms and an operating room
- d. Use of STOPNC's equipment, including (1) a fluoroscopy (x-ray) machine to provide the physician with a real-time imaging of the patient's spine and (2) equipment to monitor the patient's vital signs, both used during the procedure
- e. The medications administered during the procedure, including the steroid, contrast dye, saline, and local anesthetic
- f. The medical supplies used during the procedure, including latex gloves, gauze, and bandages
- g. Administrative services such as recordkeeping, billing, and scheduling.²⁵

RESPONSE: Denied. Billing statements for plaintiffs such as Mae Parman indicate a charge for "INJECTION, SINGLE" or "INJECTION SINGLE DIAGNOSTIC OR"²⁶ Those

²³ Culclasure Aff. ¶ 10.

²⁴ The charge varied somewhat based on the precise type of injection performed.

²⁵ Culclasure Aff. ¶ 11.

²⁶ Dkt. No. 2464-1 at PageID 21 and 23.

billing statements say nothing about a “facility fee.”²⁷ According to contracts between Saint Thomas Neurosurgical and payors such as Blue Cross Blue Shield of Tennessee, the injection charges specifically include reimbursement for drugs provided to patients.²⁸

13. A separate billing code exists for charging separately for medication administered to patients.²⁹

RESPONSE: Denied. The PSC further states that billing codes of HCPCS J1040, J1020 and J1030 could be used to bill for the steroid injection; however, Plaintiffs believe that some (if not most) third-party payors would not separately reimburse for these codes. In fact, in the 2012 ambulatory surgery fee schedule, Medicare (which many third party payors follow) indicates that these codes are “packaged service/item; no separate payment made.” As such, the Saint Thomas Neurosurgical Defendants would have no reason to bill for these codes since the cost of the steroid would need to be covered in what third-party payors would actually reimburse. According to contracts between Saint Thomas Neurosurgical and payors such as Blue Cross Blue Shield of Tennessee, the injection charges specifically include reimbursement for drugs provided to patients.³⁰

14. STOPNC did not submit a separate charge to the Plaintiffs or their insurers specifically for the MPA.³¹

RESPONSE: Disputed as more fully explained in the PSC’s response to Statement Numbers 10 and 13, which are incorporated by reference to the response to this Statement.

15. STOPNC did not collect sales tax from the Plaintiffs or their insurers for the MPA.³²

RESPONSE: Admitted for purposes of summary judgment. However, sales tax is not required to be charged for the sale MPA under Tennessee law. *See* Tenn. Code Ann. § 67-6-320.

16. Many of the Plaintiffs are Medicare beneficiaries.³³

²⁷ *Id.*

²⁸ Williams Tr., Ex. 517. The PSC previously filed this document under seal with the Court at Dkt. No. 2261-7.

²⁹ *See* PSC’s Responses to Requests for Admissions 1 and 2 and PSC’s Supplemental Response to Interrogatory No. 1.

³⁰ Williams Tr., Ex. 517. The PSC previously filed this document under seal with the Court at Dkt. No. 2261-7.

³¹ Butler Aff. ¶ 10.

³² Butler Aff. ¶12.

³³ Butler Aff. ¶ 8.

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion and involves allegations related to individual Plaintiffs. The PSC does not have access to all relevant medical records to determine how many Plaintiffs receive Medicare benefits. Regardless, Plaintiffs will admit this for the sole purpose of summary judgment that some of the Plaintiffs received Medicare benefits.

17. STOPNC billed Medicare beneficiaries and non-Medicare patients in the same manner (*i.e.*, using the same billing codes). The only difference was the reimbursement received by STOPNC, which varied to some degree based on the payor.³⁴

RESPONSE: Admitted for purposes of Summary Judgment.

18. STOPNC did not deduct the cost of the medical supplies used during the Plaintiffs' procedures as "costs of goods sold" from its income for tax purposes.³⁵

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion. Moreover, the PSC specifically requested that Saint Thomas Neurosurgical produce its income tax returns as part of the common discovery phase of this litigation. Saint Thomas Neurosurgical refused to do so, but at this late hour it now produces a single redacted page from a single years tax return in support of its cross motion for summary judgment.³⁶ The PSC should not be compelled to respond to this request until and unless Saint Thomas Neurosurgical provides a full response to the PSC's discovery requests on this issue. To the extent that Saint Thomas Neurosurgical refuses to produce documents responsive to the PSC's discovery requests for tax returns, then this statement should be stricken from the record.

19. Dr. Culclasure typically administered 80 mg of MPA (a single vial) to the Plaintiffs during their procedures.³⁷

RESPONSE: Admitted for purposes of Summary Judgment.

20. However, for some Plaintiffs, Dr. Culclasure administered 120 mg of MPA (one

³⁴ Butler Aff. ¶ 9.

³⁵ Butler Aff. ¶ 13.

³⁶ A copy of Saint Thomas Neurosurgical's responses to the PSC's requests for these documents are attached as Exhibit A.

³⁷ Culclasure Aff. ¶ 12.

and a half vials) during their procedures.³⁸

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion and involves allegations related to individual Plaintiffs. The PSC does not have access to all relevant medical records to determine how many Plaintiffs received more than one vial in each of their injections. Regardless, Plaintiffs will admit for the sole purpose of summary judgment that some of the Plaintiffs received more than one vial of MPA during their steroid injections.

21. STOPNC's charge for the procedure remained the same, regardless of the number of vials of MPA used by Dr. Culclasure.³⁹

RESPONSE: Disputed. Patients did not go to Saint Thomas Neurosurgical for a "procedure." They went to that facility to receive an injection of medicine intended to relieve pain. In addition, this statement is immaterial for purposes of ruling on the current summary judgment motion and involves allegations related to individual Plaintiffs. The PSC does not have access to all relevant medical records to determine how many Plaintiffs received more than one vial in each of their injections and how charges for these Plaintiffs reflected this oddity. Regardless, Plaintiffs will admit for the sole purpose of summary judgment that some of the Plaintiffs received more than one vial of MPA during their steroid injections, and it appears that Saint Thomas Neurosurgical received the same reimbursement regardless of how much MPA was used during the procedure.

22. If Dr. Culclasure used only part of a vial of MPA, the remainder was destroyed.⁴⁰

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion and involves allegations related to individual Plaintiffs. The PSC does not have access to all relevant medical records to determine how many Plaintiffs received more than one vial in each of their injections. Regardless, Plaintiffs will admit for the sole purpose of summary judgment that some of the Plaintiffs received more than one vial of MPA during their steroid injections and that Saint Thomas Neurosurgical likely destroyed the remaining MPA.

23. STOPNC performs the following procedures to treat its patients' pain: steroid injections, radiofrequency ablations (denervations), spinal cord stimulator trials, diagnostic facet joint injections, hardware blocks, and nerve root blocks.⁴¹

³⁸ Culclasure Aff. ¶ 12.

³⁹ Culclasure Aff. ¶ 13.

⁴⁰ Culclasure Aff. ¶ 14.

⁴¹ Culclasure Aff. ¶ 5.

RESPONSE: Disputed. Patients did not go to Saint Thomas Neurosurgical for a “procedure.” They went to that facility to receive an injection of medicine intended to relieve pain. In addition, this statement is immaterial for purposes of ruling on the current summary judgment motion. The PSC further disputes the content of this statement as the testimony of Debra Schamberg shows that Saint Thomas Neurosurgical only provided denervations in addition to epidural steroid injections (other than steroid injections) in 2011 and 2012.⁴²

24. During a radiofrequency ablation, the nerves causing the patient’s back or neck pain are heated using radio waves.⁴³ When the procedure is successful, the heat leaves a lesion on the nerve that prevents pain signals from reaching the brain, providing pain relief.⁴⁴

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion. These motions involve steroid injections performed at Saint Thomas Neurosurgical. This statement is simply not relevant to the inquiry. Regardless, the PSC will admit for the sole purpose of summary judgment.

25. Radiofrequency ablations do not rely on medication to provide pain relief.⁴⁵

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion. These motions involve steroid injections performed at Saint Thomas Neurosurgical. This statement is simply not relevant to the inquiry. Regardless, the PSC will admit for the sole purpose of summary judgment.

26. STOPNC is typically reimbursed approximately \$370 for epidural steroid injections by patients or their insurers.⁴⁶

RESPONSE: Admitted for purposes of summary judgment.

27. The medical supplies used during an epidural steroid injection, including the MPA, typically cost less than \$40 total.⁴⁷

RESPONSE: This statement is immaterial for purposes of ruling on the current summary judgment motion. Regardless, Plaintiffs will admit for purposes of summary judgment.

⁴² Schamberg Tr., Pg. 49:25-50:14 and 285:7-25, copies of this transcript are attached hereto as Exhibit B.

⁴³ Culclasure Aff. ¶ 15.

⁴⁴ Culclasure Aff. ¶ 15.

⁴⁵ Culclasure Aff. ¶16.

⁴⁶ Butler Aff. ¶ 11.

⁴⁷ Butler Aff. ¶ 14.

28. STOPNC has contracts with BlueCross BlueShield of Tennessee, Cigna HealthCare of Tennessee, and MissionPoint Health Partners.⁴⁸

RESPONSE: Admitted for purposes of summary judgment.

Dated: December 15, 2015

Respectfully submitted,

/s/ J. Gerard Stranch, IV

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⁴⁸ Butler Aff. ¶ 15.

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, J. Gerard Stranch, IV, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: December 15, 2015

/s/ J. Gerard Stranch, IV
J. Gerard Stranch, IV